

Online Research @ Cardiff

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository: <https://orca.cardiff.ac.uk/id/eprint/124472/>

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Ali, F.M., Salek, M.S., Finlay, A.Y. ORCID: <https://orcid.org/0000-0003-2143-1646> and Piguet, V. 2019. Validation of the electronic Psoriasis Area and Severity Index application: establishing measurement equivalence. Journal of The American Academy of Dermatology 81 (6) , pp. 1439-1441. 10.1016/j.jaad.2019.04.073 file

Publishers page: <http://dx.doi.org/10.1016/j.jaad.2019.04.073>
<<http://dx.doi.org/10.1016/j.jaad.2019.04.073>>

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies.

See

<http://orca.cf.ac.uk/policies.html> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



Title Page

Validation of the electronic PASI application: establishing measurement equivalence

FM Ali¹ (MBChB), MS Salek^{2,3} (PhD), AY Finlay¹ (MBBS), V Piguet^{1,4} (MD),

¹Department of Dermatology and Academic Wound Healing, Division of Infection and Immunity, School of Medicine, Cardiff University, Cardiff, UK

²School of Life and Medical Sciences, University of Hertfordshire, Hatfield, UK

³Institute for Medicines Development, Cardiff, UK

⁴Division of Dermatology, Department of Medicine, University of Toronto; Division of Dermatology, Women's College Hospital, Toronto, Canada

Running head: Validation of electronic PASI

*Correspondence:

- Dr Faraz Ali, Department of Dermatology, Division of Infection and Immunity, School of Medicine, Cardiff University, 3rd Floor Glamorgan House, Heath Park, Cardiff CF14 4XN, UK
email: AliFM@cardiff.ac.uk, tel: +44 29 2074 5874

Funding: The study was supported by a research grant from Janssen-Cilag Limited

Conflicts of Interest

FA has received travel expenses for attending AAD meetings from Janssen-Cilag Limited. FA has received lecture fees from Leo Pharmaceuticals.

AYF is joint copyright owner of the DLQI. Cardiff University and AYF receive royalties. AYF is a member of a Novartis Advisory Board and has received lecture fees and travel expenses from Novartis.

VP undertakes personal advisory work for Pfizer, AbbVie, Janssen, UCB, Novartis, Almirall and Celgene. He has received departmental support from AbbVie, Bausch Health, Celgene, Janssen, LEO Pharma, Lilly, NAOS, Novartis, Pfizer, Pierre-Fabre, and Sanofi.

Keywords: electronic, validation, equivalence, PASI, clinical outcome measures

Letter word count: 498

Manuscript table count: 1

Manuscript figure count: 1

ORCID Numbers:

Faraz Ali: 0000-0002-4184-2023

Sam Salek: 0000-0002-4612-5699

Andrew Finlay: 0000-0003-2143-1646

Vincent Piguet: 0000-0001-6079-4517

Despite its many shortcomings, the Psoriasis Area and Severity Index (PASI) remains the standard method worldwide for psoriasis assessment¹. Several studies have implemented electronic versions without evidence of formal validation, raising the possibility of lack of equivalence with the paper counterpart². This study aimed at comparing the conventional paper-based and a novel electronic application version of the PASI (Figure 1). International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines³ were followed to assess rater preference and consistency of scores.

The study employed a randomized cross-over design using a within-subjects comparison of the two formats of the PASI. The study was conducted at the dermatology outpatient department, University Hospital of Wales, Cardiff, UK. Inclusion criteria were: patients aged 18 years or older with a clinical diagnosis of chronic plaque psoriasis from a dermatologist and the ability to read and understand English. Raters ranged from medical students to senior trainees and received standardised clinical training for PASI assessment to ensure uniformity of rating. The study power was 80%, with an expected intra-class correlation coefficient (ICC) of 0.9 ($\alpha = 0.05$), resulting in a target sample size of 44 patients.

All three raters showed high correlation in test scores (Pearson-correlation 0.949, $p < 0.05$, $n = 5$) demonstrating standardisation of the assessment criteria. Forty-four patients were recruited, mean age 45 years ($SD \pm 16$, 59.1% male). The mean duration of chronic plaque psoriasis diagnosis was 19.2 years ($SD \pm 14.8$, interquartile range, IQR, 8-30), with PASI severity ranging from 0.7 to 28.5. The ICC showed high concordance between the total PASI scores from paper and iPad

format (ICC = 0.993; 95% CI 0.988-0.996, Table 1). The median difference in PASI scores was also within the hypothesized difference of CC = 0.993 (p=0.72). The lower and higher limits of agreement were -1.4 and 1.4, respectively.

The PASI iPad® version demonstrated reduced inter-rater variability compared to the paper version (Pearson correlation 0.982 vs 0.949, number of patients assessed=5). There was no carryover effect demonstrated with scores (p=0.82) or time to completion (p=0.16) regardless of which format of the PASI was used first. The raters, using a stopwatch, took a median of 147 seconds (iPad®) versus 152 seconds (paper), not including calculation time (p=0.81). Raters reported that the iPad version was easier to use compared to the paper version due to the visual nature of the application allowing accurate assessment and calculation of severity scores, though suggestions were made to improve the user interface.

The future of medical practice is intricately anchored within the evolution of digital technology. There is high correlation, and thus equivalence, between the PASI iPad® and paper versions. The raters preferred the iPad version due to the visual nature of the scoring process and the reduced likelihood of calculation errors. The higher inter-rater reliability and the inherent advantages of electronic tools⁴ further re-enforces the superiority of the digital format. The validated Psoriasis 360 application®, together with the previously validated DLQI⁵ component, has the potential to be of considerable value to clinicians, researchers and patients.

REFERENCES

1. Ashcroft DM, Wan Po AL, Williams HC, Griffiths CEM. Clinical measures of disease severity and outcome in psoriasis: a critical appraisal of their quality. *Br J Dermatol* 1999;**141**:185-191.
2. Campbell N, Ali F, Finlay AY *et al*. Equivalence of electronic and paper-based patient-reported outcome measures. *Qual Life Res*. 2015;**24**:1949-61.
3. Coons SJ, Gwaltney CJ, Hays RD *et al*. Recommendations on Evidence Needed to Support Measurement Equivalence between Electronic and Paper-Based Patient-Reported Outcome (PRO) Measures: ISPOR ePRO Good Research Practices Task Force Report. *Value Health*. 2009;**12**:419-29
4. Gill JM, Ewen E, Nsereko M. Impact of an electronic medical record on quality of care in a primary care office. *Del Med J* 2001;**73**:187-94.
5. Ali FM, Johns N, Finlay AY, Salek MS, Piguet V. Comparison of the paper-based and electronic versions of the Dermatology Life Quality Index: evidence of equivalence. *Br J Dermatol* 2017;**177**:1306-15.

TABLES

Table 1 Equivalence analysis of paper and electronic PASI overall mean scores and mean completion time

	Paper	iPad®	ICC* (95% CI)	Difference (P – I)	Limits of agreement‡	
PASI scores (n=104)					lower	upper
<i>Median (IQR)</i>	5.7 (2.1-10.7)	5.8 (2.7-9.3)	0.993 (0.988 – 0.996)	0.0 (-0.3 – 0.4)†	-1.4	1.4
PASI times (mins:seconds)						
<i>Median (IQR)</i>	2:32 (01:55-03:07)	2:27 (01:54-03:00)	0.444 (0.148 – 0.665)	-00:10 (-00:31-00:40)†		

CI = confidence interval, ICC = intraclass correlation, IQR = interquartile range, SD = standard deviation

P-I = Paper - iPad®

* Hypothesizing coefficient of ≥ 0.9

† p value > 0.05 calculated by Wilcoxon Signed Rank test

‡ Limits of agreement calculated from Bland-Altman plots

Figures

Figure 1 Example screenshot from the PASI iPad App

